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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,940	03/07/2000	MICHAEL C CRESS	212662-1	8849

7590 07/28/2004

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,940

Applicant(s)

CRESS ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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Re: Cress *et al.*

Date of priority: 06/02/1998

Request for Continued Examination

The request filed on 01-09-2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/424940 is acceptable and a RCE has been established.

An action on the RCE follows.

Claims 1-21, 23 are cancelled.

Claims 22, and 24-27 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 22, and 24-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wojtukiewicz *et al.* (Polish Jnl. Pharm., 1996, Vol. 48, pages 229-232) and US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989) for the reasons of record in the Action mailed 07/11/2003.

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Applicants primarily argue (Response, originally filed 01/09/2004 and repeated on 05/10/2004) that new limitations to claim 22 are not taught. For example, Applicants argue (page 6) that in contrast to the teachings and suggestions of the prior art references, either alone or in combination, the present invention utilizes the primary step of “identifying the association or correlation between fibrinogen degradation products (FDP) and common oncogenic proteolytic processes indicative of the presence of a variety of cancers, not just gastric cancer, in the target mammalian or human subjects”. Applicants argue that identifying this association, an association that is absent in the prior art, is “part of the present invention methods of screening for more than one type of cancer with a high degree of specificity” and an acceptable degree of sensitivity and that this association is not disclosed or suggested in the cited references. This argument has been considered but is not found persuasive.

First, the amendment to the claim does not recite nor limit common oncogenic proteolytic processes that are “indicative of the presence of a wide variety of cancers”. Thus, the correlation between the prior art determination of an FDP epitope of the beta chain of fibrinogen and gastric cancer remains anticipatory of the newly amended invention. Arguments presented that rely on particular distinguishing features are not persuasive where those features are not recited in the claims. Secondly, the newly amended claim is vague because it does not appear to impart a distinct step in the manner of detecting cancer (see rejection below). How does identifying an association between FDP and some common oncogenic proteolytic process further define or limit the steps of detecting cancer? What is the nexus? Lastly, and moreover, it would appear that the prior art does in fact suggest or disclose this association because the presence of FDP was identified in the subject. And, as taught by the specification on page 5, line 26; a “degradation

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peptide” (such as FDP) is broadly defined as a peptide of a larger protein which has been degraded, for example, as occurs with the proteolytic degradation of “blood proteins that is observed in oncogenic processes”. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

New Rejection:***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, newly amended Claim 22 introduces the step of “identifying the association between a fibrinogen degradation product (FDP) and common oncogenic proteolytic processes” in concert with the steps of contacting and determining an FDP epitope. However, how is this association identified, and how does it relate to determining cancer in a subject? Further, what is the active step for determining this association? The specification does not appear to include this step in the method of detecting cancer. Hence, it’s not clear how this new step imparts any patentable weight to the claimed method of detecting cancer in a subject.

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All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Conclusion

This is a continuation of applicant's earlier Application No. 09/424,940. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN
07/23/04


GARY NICKOL
PRIMARY EXAMINER